

Appendix 8:

## **KESSLER OL SEMINAR WELCOMING REMARKS**

DRAFT: 10/20/98

Hello, I'd like to welcome you today to the Office of Surveillance and Biometrics seminar and workshop on Outside Leveraging. I would like to especially thank Pat Spitzig of the Front Office in OSB for her tireless dedication to making this seminar happen. In addition I would like to welcome some other very special people today to the program. First, I'd like to thank the speakers from other Agencies who have graciously agreed to share their experience with us: Mr. Winwood from the U.S. Customs Service; Ms. Tirpak from the Environmental Protection Agency; and Mr. Bob Pitulej from the Occupational Safety and Health Administration. I'd also like to thank the staff from the Department of Justice, who could not be with us but generously provided some of the material that we will be viewing today.

We also have FDA panelists from both inside and outside of CDRH who have interesting projects to tell us about. The panelists will be more formally introduced later today. I'd like to extend a special welcome to our guests from outside OSB. We have Dr. Liz Jacobson, the Deputy Director for Science at CDRH, and Mr. Phil Frappaolo one of our Reengineering Czars. We have representatives here from the Office of Chief Counsel; the Office of Science and Technology; the Office of Compliance; the Office of Device Evaluation; and the Office of Systems Management, including our Integrity Officer, Ms. Pat Bianchi and Linda Horton, Office of International Affairs. A special welcome back to Mary Jones, who is our workshop

consultant and who will be facilitating a workshop tomorrow with OSB staff exploring some of the ideas that we have for potential outside leveraging projects that we might pursue for the benefit of the FDA.

I'd like to spend a little bit of time telling you how we have gotten ourselves to this point and follow that with a description of our vision on how outside leveraging should fit into our office's future. For our guests, it is important that they know that the Office of Surveillance and Biometrics is one of six offices that comprise the Center for Devices and Radiological Health. Our mission includes postmarket surveillance of medical devices, coordination of issues that cross office lines in the center, handling all issues related to the medical device reporting data and its database, and provision of statistical consultation throughout the entire Center. As part of the Center's mission to have an overarching regulatory responsibility for medical devices as they evolve from their inception and design through postmarket evaluation on toward obsolescence, our office is in a unique position to complete part of the feedback loop in this process because of our joint pre and postmarket perspective.

The burdens of such a vast mission that OSB carries weigh very heavily on a fairly small staff. Several years ago, at times it seemed if there were more projects and activities than there were staff. Setting priorities and thinking through where the office was going proved very difficult. To attempt to make rational decisions, bring the Office to a new level of performance and ensure that it was accomplishing its most important goals, OSB launched a major strategic planning initiative. With the help of Mary Jones, our outside consultant, OSB built a strategic plan and has been following it for the past

year. Goal three of our strategic plan states, “we will establish collaborative relationships or partnerships as appropriate with customers and stakeholders to maximize the effectiveness of our programs.”

A natural sub-objective of this particular goal is the development of leveraging relationships with a wide variety of organizations that share mutual interests with OSB and with CDRH. It is our firm belief that identifying activities central to OSB’s public health mission and finding collaborating partners who share the same mission will produce exciting opportunities for shared efforts that can produce proverbial “win win” situations. One of the purposes of this two-day session is to identify and develop potential OL projects. We recognize that in some, if not all, of the cases where we hope to produce an outside leveraging project, an initial investment of time or money will be necessary before we can reap net benefits in the future.

Where does the concept of outside leveraging fit with OSB’s vision of the future? As part of our strategic plan, we envision OSB as an integral part of an interlocking network of organizations both inside and outside the federal government that collaboratively produce medical device technology for the American public at a high level of safety and effectiveness. We see our natural partners as other offices in the Center for Devices, other organizations in the federal government particularly in the public health arena, the medical device manufacturing community, the clinical and user facility communities, professional associations, academics, researchers, and the patient population which benefits from this technology. Recognizing that our mission is an expanding one in a time of fiscal constraints suggests

we have to do our job in different ways. It is almost impossible to do more of the same with less; however, with creative strategic thinking, planning and action, we can end up accomplishing our goals using fewer government resources by working in different ways. Archimedes, the gifted Greek scientist, mathematician and inventor, once said, “Give me a place to stand and rest my lever on, and I can move the earth.” The “lever” allows the amount of effort required moving the mass to remain constant while the mass to be moved can grow in size and /or weight. We are here today seeking to create the philosophical levers, those strategic alliances that will allow us to move the mass of work more easily and effectively. Outside leveraging is one concept which we believe will help OSB realize its mission and improve the public health in the United States in tangible ways. I want to thank you for your participation in our workshop today and solicit your creative thinking and support in the future as we pursue viable OL projects.

We don’t have a “cookbook” solution for outside leveraging. What we do have are the stories of some innovative pioneers who have dared to think and act differently to address tough challenges in government and are willing to share their lessons learned with us so that we may benefit from their ground breaking experience. I invite you all to listen, explore solutions and learn with us. I will now turn the platform over to Ms. Pat Spitzig.... Pat (?)

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